UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/720,603 | 11/24/2003 | Ananda M. Chakrabarty | 51282-00013 | 6398 |

7590 11/16/2007

Sheppard Mullin Richter & Hampton LLP
1300 I Street NW
11th Floor East
Washington, DC 20005-3314

| EXAMINER | |
|---|---|
| YAO, LEI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 11/16/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/720,603 | CHAKRABARTY ET AL. | |
| | Examiner | Art Unit | |
| | Lei Yao, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,5,7 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Request for Continued Examination**

The request filed on 10/25/2007 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10720603 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 1, 2, 5, 7, and 20 are currently pending and are under consideration. It is noted that applicant has cancelled the claims reciting elected species plastocyanin, SEQ ID NO: 2, in response to the restriction requirement dated 9/15/2006 and now has limited the scope of claimed method to use azurin and its derivatives.

***Claim Rejections - 35 USC § 112-scope of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 7, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a condition related to resistance to cell death comprising administering to a patient a pharmaceutical composition of wild type azurin of SEQ ID NO: 1 does not reasonably provide enablement for the method of administering any other mutated or truncated azurins (claims 1-2) comprising amino acid sequences of SEQ ID NO: 6, 7, 45, 46, 47, 48, 50, 51, 52, and 53 (claim 7) for treating any condition comprising melanoma (claim 20). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factor considered when determining if the disclosure satisfies the enablement requirement and whether any is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of necessary experimentation claims, 7) amount of

direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re wands,* 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir.1988).

The claims are broadly drawn to a method of treating a condition related to resistance to cell death comprising melanoma comprising administering to a patient a pharmaceutical composition with any mutated or truncated azurin or defined mutated truncated azurin represented by amino acid sequences of SEQ ID NO: 6, 7, 45, 46, 47, 48, 50, 51, 52, or 53 listed in claim 7. Based on the claimed invention, it would be expected that one of skill in the art would be able to treat a condition with any azurin recited in the claims without undue experimentation by using the claimed method.

To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The specification on page 44-47 (examples 15-16 and 18) describes in vivo treating mice with azurin with or without other agent. For the enablement disclosure of claimed invention, examples 16 teaches that mice with melanoma tumor were treated with wild type azurin plus M. *Bovis* column chromatographic fractions (QSFT, figure 8). The specification does not provide an in vivo method treating a condition to induce tumor cell death in a subject with any mutated or truncated azurin comprising the mutants having amino acid sequence of SEQ ID NO: 6, 7, 45, 46, 47, 48, 50, 51, 52, or 53 listed in claim 7. The specification although provides the structure and in vitro cell based cytotoxicity assay of some of those mutants, the in vitro assay indicates that the most of the tested mutated or truncated azurin do not work as well as the wild type of azurin in term of the cytotoxicity to the tumor cells (figure 12-13). The method of using mutated azurin, M44KM64E, SEQ ID NO: 7 shows minimal cytotoxic activity to the cells (figure 12) and apoptosis rate (figure 13). In addition, more importantly, claimed invention is drawn to *in vivo* treating a condition with mutated or truncated azurin, the specification shows neither the result of in vivo treatment with any of the mutants of azurin (except wild type azurin), nor correlation between the in vitro cytotoxic activities and *in vivo* treatment in a patient for any condition comprising melanoma. Thus, in the absence of this guideline, direction and experimentations, one skilled in the art would

be unable to use claimed invention without undue quantity of experimentations because of unpredictability of the nature of the invention.

Moreover, one skilled in the art has also recognized that the mutated or truncated form of a toxin may not always have the same activities as its wild type form. For example, Yamada et al., (PNAS, vol 99, page 14098-14103, provided before) show "mutations in two critical amino acids Met-44 and Met-64 of azurin have been shown to lead to a loss >95% of the azurin electron transfer activity. The assay for cytotoxicity of the azurin against a human melanoma cell line UISO-Mel-2 demonstrates that the M44K/M64E mutant has very little cytotoxicity compared to the wild type of azurin (Fig. 2*B, page 14100 col 1*). Yamada et al., further teach that M44KM64E mutant being deficient in cytotoxicity toward a p53 null cell line UISO-Mel-6 cells is due to deficient in forming a complex with p53.

With regards to the correlation between in vitro assays and *in vivo* models, the state of the art recognizes that *in vitro* assays and/or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are unpredictable and generally lacking. The greatly increased complexity of the *in vivo* environment as compared to the very narrowly defined and controlled conditions of an *in- vitro* assay does not permit a single extrapolation of *in vitro* assays to human diagnostic efficacy with any reasonable degree of predictability. *In vitro* assays cannot easily assess cell-cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4, provided before) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative

of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences In Vitro). Further, Dermer (Bio/Technology, 1994, vol12, page 320, provided before) teaches that, petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells *in vivo* are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those *in vivo* and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell interactions. Further, treatment of cancer in general is at most unpredictable, as underscored by Gura (Science, vol 278, page1041-1042, 1997, provided, before) who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from in-vitro to in-vivo protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. All of this underscores the criticality of providing workable examples, which is not disclosed in the specification, particularly in an unpredictable art such as cancer therapy. Because claimed method of *in vivo* treatment a condition comprising melanoma is unpredictable undo experimentation would be necessary and required for the claimed invention

Thus, in view of the lack of guidance, lack of examples, and lack of predictability associated with regard to the usage of any mutated or truncated azurins comprising amino acid sequences of SEQ ID NO: 6, 7, 45, 46, 47, 48, 50, 51, 52, or 53, one skilled in the art would be forced into quantity of undue experimentations in order to practice the claimed invention.

Response to applicant argument to the final rejection under 35 USC 112-enablment

The response filed 10/25/2007 has been carefully considered but is deemed not to be persuasive. Applicant argues the following.

A. The examiner's rejection fails to separately address each claims and stated below:

> The Examiner's analysis focuses entirely on the enablement requirement's application to claim 1. Notably absent from the Examiner's discussion of the rejection of claims 2, 7 and 20 is any discussion of the limitations of claims 2, 7 or 20. It is a matter of fundamental patent law that patentability is determined on a claim-by-claim basis; the Examiner ignores this most basic of principles and rejects eleven claims based upon an analysis of a single claim. For this reason alone, the Examiner's rejections of claims 2, 5, 7 and 20 should be reconsidered and withdrawn.

In response, first, new rejection is formed in this Office action to state each limitation of rejected claims. Second, the rejection in final action dated on 8/8/2007 is also formed based on the fundamental patent law that patentability determined on a claim-by-claim basis. The dependent claims 2, 7, and 20 are further drawn to base claim 1, wherein the mutated or truncated azurin binds to p53 (claim 2) and wherein the mutated or truncated azurin has amino acid sequence represented by SEQ ID NO: 6, 7, 45, 46, 47, 48, 50, 51, 52, or 53 (claim 7), wherein the condition is melanoma (claim 20). Applicant is reminded that these dependent claims include all the limitation of base claim 1 that is drawn to a method of administering any mutated or truncated azurin to treat a condition. The current and/or previous rejection is formed because the specification does not reasonably provide enablement for the method of administering any mutated or truncated azurin and/or the mutated azurin having amino acid sequences of SEQ ID NO: 6, 7, 45, 46, 47, 48, 50, 51, 52, and 53 to treat any condition comprising melanoma. This rejection would include dependent claims (1, 2, 7,and 20), which has not further limited the mutated or truncated azurin to specific one that specification has provided enablement disclosure for it. Applicant is noted, claim 5 is further limited claim 1 to wild type azurin (SEQ ID NO:1), therefore, claim 5 is not rejected under such statutory basis. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, claims 1, 2, 7,and 20.

B. The Examiner errs by requiring in vivo data and deeming in vitro data insufficient and stated below:

> The Examiner goes on to provide an analysis of the differences between in vivo and in

> vitro data. Id. at pages 8-10. The Examiner does not address the manner in which the law analyzes the two types of data. See id. As Applicants explained in their response to the Examiner's written description rejection, the law simply does not require in vivo testing data to support claims to the use of a compound to treat a patient. See MPEP § 2107.03. The Examiner's requirement is thus contrary to the law and improper. For this reason, Applicants respectfully request reconsideration and withdrawal of the Examiner's enablement rejections of claims 1, 2, 5, 7 and 20.

In response, on page 8-10 of previous office action dated 8/8/2007 and here again set forth above, the rejection explicitly discusses and explains that the requirement of in vivo result is necessary for the invention claiming administering a patient with mutated or truncated azurin. Although as indicated by applicant the law does not require in vivo testing data to support claims to the use of a compound to treat a patient, the level of predictability in the art, amount of direction or guidance by the inventor and/or quantity of experimentation are necessary to support the claimed invention being enabled. If no in vivo data is provided, the correlation in vitro and in vivo result, predictability and/or guideline would be essential and important to direct one skilled in the art to use or practice claimed invention without undue experimentation. However, the instant specification does not provide any of them and instead, in vitro assay of cytotoxicity and apoptosis has shown the less activity of the mutated azurin than their wild type azurin. Thus, how can one skilled in the art practice those mutants on a patient for cancer treatment without a quantity of undue experimentations?

C. The Examiner errs in requiring that the subject compounds have identical properties and stated below:

> the Examiner is seemingly requiring the relevant genus of compounds to have identical functionalities or, perhaps more specifically, identical levels of functionality. However, the Examiner is incorrect in imposing such a requirement. Per the claims, the compounds must "promote death in a cell demonstrating resistance to cell death." Claim 1. That some compounds in the group do this better than others is not relevant to the enablement issue. Moreover, that some compounds in the genus are wholly inoperable is also not strictly relevant to the enablement inquiry. What is important is whether one of skill in the art could identify such embodiments without undue experimentation, which clearly is the case here.

In response, the Office does not require the compounds (mutated or truncated azurins) in the claimed method have the same activity as wild type azurin for treating a patient. However, the Office does require application providing objective evidence to show that claimed method is enabled. The Office does note the in vitro assay showing the lower or less activity of the mutated or truncated azurin on the tumor cell cytotoxicity and apoptosis compared to the wild type of azurin in the application. The application does not provide any evidence or showing that those mutated or truncated azurins with less activity could be practiced in vivo for treating a patient by one skilled in the art based on those in vitro assay and before quantity of undue in vivo experimentations.

D. The subject compounds share a common, highly conserved structure corresponding to their functionality and stated below:

> The cytotoxic cupredoxins are described in the specification as sharing a common, highly conserved structure which includes, inter alia, a beta-barrel structure, a copper binding site consisting of a cluster of four residues, and a hydrophobic patch involved in binding interactions with various partners, including p53. See paragraphs [073-085]. Additionally, as described above, it is known in the art that azurins have a G-H loop sequence which has great binding affinity for ephrinB2 and which exhibits a cytotoxic effect.

In response, again, claims are drawn to a method of treating a patient with mutated or truncated azurin. Thus, it would be expected that one of skill in the art would be able to treat a patient with any azurin recited in the claims without undue experimentation by using the claimed method. Listing mutated or truncated azurins containing certain structure such as cupper binding site or hydrophobic patch for the binding of some proteins including p53 does not render the claimed method enabled for treating a patient in vivo because applicant does provide enough evidence that the cytotoxicity and apoptosis of those azurins is induced by interaction of p53 with the azurin. Again, instant specification does not any teaching on treating any patient with any mutated or truncated form of the azurins. Instead, the in vitro assay shows that the mutated azurins have less activity than wild type of azurin in the cell death.

In summary, as stated above, to satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. Instant application does not provide objective evidence, guideline, direction, or predictability to allow one skilled in the art to practice claimed invention without undue quantity of experimentation. Thus, Applicant's argument has not been found persuasive, and the rejection under USC 112, 1st paragraph, lack of enablement, is maintained and made again above.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. In reBerg, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998): In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993): In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Patent No. 7084105

1. Claims 1, 5, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 7-12 of US patent No. 7084105. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant amended claims 1, 5, and 20 are drawn to a method of treating a condition comprising administering to a patient azurin (SEQ ID NO: 1), or truncated azurin to promote cell death, wherein the condition is human melanoma.

Claims 1-3, 5, and 7-12 of US Patent No. 7084105 are drawn to method of treating a cancer comprising melanoma comprising administering to a patient azurin, or truncated azurin, wherein the compound azurin modulate cell death.

Both sets of claim are directed to a method of treating a condition comprising melanoma by administering to a patient azurin or truncated azurin. The claims of US Patent 7084105 also include treating the disease with other cancer agent in combination and instant claims include promoting resistant cell death. Thus, the only difference between the two sets of claims is the scope of the claims. Because both set of the claims encompass a method of treating the same condition with the same materials the claim(s) is obvious over each other.

2. Claims 1 and 2 are on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 7-12 of US patent No. 7084105 in view of Yamada et al., (PNAS, vol 99, page 14098-14103, Oct. 2002, applicant's IDS A23).

Claim 1 of instant application is set forth above. Claim 2 is further drawn to claim 1 above, wherein azurin binds to tumor-suppressor protein p53 to promote cell death.

Claims 1-3, 5, and 7-12 of US Patent No. 7084105 are set forth above.

Claims US Patent No. 7084105 do not teach azurin binding to p53 to promote cell death,

Yamada et al., disclose azurin binding to tumor suppressor protein p53 and form a complex to induce cell death and regression of cancer (figure 5 and bridge page 14101-2).

It would have been *prima facie* obvious at the time the claimed invention was made to use the method described in claims of US Patent 7084105. One of ordinary skill in the art would have been motivated with reasonable expectation of success to combine the methods to treat a patient with a cancer by promoting cancer cell death by binding to p53 according to the teaching of claims US patent No. 7084105 because the claims of US patent have shown the method of using azurin to treat cancer and Yamada have shown that azurin binds to p53. Therefore, the claimed invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention as made, as evidenced by the claims of US Patent 7084105 in combination of Yamada's.

Application No. 11488693 (693').

Claims 1,5, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 of copending Application No.11488693 (693'). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1, 5, and 20 of instant application are drawn to a method of treating a condition related to resistant to cell death comprising administering an effective amount of effective amount of azurin or mutated or truncated azurin, wherein resistance to cell death is human melanoma.

Claims 19-22 of 693' are drawn to method of treating patient suffering inappropriate angiogenesis comprising administering to a patient with a therapeutically effective amount of a cupredoxin, wherein suffering is melanoma.

The claims in the instant application and claims in application 693' are directed to a method of treating patient suffering from proliferative or cancer related disease comprising administering to a patient with a therapeutically effective amount of a cupredoxin comprising azurin. The differences among the claim sets is that cancer related disease is resistant to cell death in the instant application and angiogenesis in the application 693', in which both are related with cancer comprising melanoma development and occurring and also instant claims encompass one species of cupredoxin, azurin, while the claims of application 693' are drawn to the genus of cupredoxin.

It would have been *prima facie* obvious at the time the claimed invention was made to use the one or more species of cupredoxin in method to treat the melanoma. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to use the method to treat a patient with melanoma because claims in application 693' has shown method of treating patient suffering angiogenesis comprising administering to a patient with a therapeutically effective amount of a cupredoxin, wherein suffering is melanoma.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application No. 11244105 ('105)

Claims 1, 5, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 24 of copending Application No. 11244105 ('105). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1, 5, and 20 of instant application are drawn to a method of treating a condition related to resistant to cell death comprising administering a patient an effective amount of azurin or mutated or truncated azurin, wherein the condition is melanoma.

Claim 24 of application'105 is drawn to method of treating patient with cancer with a complex of cargo compound and truncation of a full-length wild type of cupredoxin that comprise azurin

Both sets of claim are directed to a method of treating a condition comprising cancer or melanoma by administering to a patient a truncated cupredoxin comprising azurin or truncated azurin. The claims of application '105 also include treating cancer with the cupredoxin in a cargo compound to facilitate the entry to a cell. Thus, the only difference between the two sets of claims is the scope of the claims. Using a cargo compound to facilitate the therapeutic agent to entry to a cell is within the purviews of one skilled in the art. Because both set of the claims encompass a method of treating the same a condition, cancer with the same materials the claim(s) is obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yamada et al., (PNAS, vol 99, page 14098-14103, provided in previous office action) teach that wild type of azurin exhibit cytotoxicity to melanom tumor or mice with the tumor.

Yamada et al., do not teach or suggest treating resistant to cell death by administering truncated or mutated form of cupredoxin or plastocyanin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600